



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/127,059	07/31/1998	AMEDEO LEONARDI	648/1D340-US	9662

7590 08/12/2003  
ROBERT C SULLIVAN  
DARBY & DARBY  
805 THIRD AVENUE  
NEW YORK, NY 10022

EXAMINER

BERNHARDT, EMILY B

ART UNIT	PAPER NUMBER
----------	--------------

1624

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/127,059

Applicant(s)

LEONARDI et al.

Examiner

Emily Bernhardt

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1) ☒ Responsive to communication(s) filed on 7/24/03 (RCE Request)

2a) ☐ This action is FINAL.

2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4) ☒ Claim(s) 1-5 and 19-21 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) ☒ Claim(s) 3 and 19-21 is/are allowed.

6) ☒ Claim(s) 1, 2, 4, and 5 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some\* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) ☐ Notice of Informal Patent Application (PTO-152)

3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

6) ☐ Other:

Art Unit: 1624

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/24/03 has been entered. As applicants have requested the after final amendment of 12/20/02 has been entered.

Claims 1,2,4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as ~~being indefinite for failing to particularly point out and distinctly claim the subject~~  
matter which applicant regards as the invention.

1. The preamble to the B definition, choice (b) in main claim 1 is misleading since only naphthyl is expressly recited. Its deletion is suggested.
2. A typo is noted in claim 2. Note "CN" should read as "C-CN".

Claims 1,2,4 and 5 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a

Art Unit: 1624

way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

1). As stated in the Advisory Action, the variable B is no longer directly attached to the piperazine ring but now is on the phenyl- not originally described. Additionally, the hetero ring scope is broader than the original proviso (1) as stated in the specification on p.3 for "heteroaryls" and the instant claim language includes not only heteroaromatics but **saturated, non-aromatics** as well. Also the optional substitution for these rings is not seen anywhere in the original disclosure. The substituents listed on p.5 of the specification are described as being for "aryl" groups. Defining B to be either phenyl or naphthyl optionally substituted with

---

~~monovalent substituents as listed in main claim 1 or (b) phenyl which is fused to~~  
form benzodioxanyl or (c) represents phenyl ring which is fused to form indolyl  
would overcome new matter and scope of claim issue applied below;

2). The amendment to proviso #1 also lacks descriptive support in the disclosure as originally filed. The new proviso requires certain groups can only be present on phenyls as Ar/Ar' based on the nature of the Y variable which is not seen to be described by way of a preference for the new subgenus in the disclosure as

Art Unit: 1624

originally filed. Note Ex parte Winters, 11 USPQ 2d 1387 and Ex parte Grässelli 231 USPQ 393 regarding new matter problems when narrowing the claims.

Claims 1, 2, 4 and 5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for benzodioxinyl and indolyl, does not reasonably provide enablement for any other benzofused ring systems as generically embraced by the present claim language. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Specification provides no guidance as to what other ring systems might be suitable

~~and there is no basis in the prior art directed to similar compounds having the same~~

activity as herein. There is thus no reasonable basis for assuming that the myriad of compounds embraced by the claims will all share the same physiological properties since they are so structurally dissimilar as to be chemically non-equivalent. Note In re Surrey 151 USPQ 724 regarding sufficiency of disclosure for a Markush group.

Also see MPEP 2164.03 for enablement requirements in cases directed to structure-sensitive arts such as the pharmaceutical art. Also note the criteria for enablement

Art Unit: 1624

as set out in *In re Wands* cited in MPEP 2164.01(a), August 2000 edition. Thus given the breadth of the claims, the level of unpredictability in the art and the lack of direction (i.e. working examples) provided as to what other ring systems might work this rejection is applied.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,2,4 and 5 remain rejected under 35 U.S.C. 103(a) as being unpatentable over *Shiota* for reasons of record. In the Advisory action the examiner indicated the foreign priority document provided to antedate this reference was incomplete and the claims otherwise are not entitled to 119 benefit in view of the ~~new matter rejection still present.~~

---

Claims 1,2,4 and 5 remain rejected under 35 U.S.C. 103(a) as being unpatentable over *Janssen* (US'367). While proviso #1 has been modified to exclude both of Ar/Ar' as being unsubstituted and one not alkyl-substituted, the compounds of *Janssen* remain obvious variants. Note the *Fauque* decision cited by the examiner in a previous action in which the presence of 2 methyl groups on separate rings (in this case the Ar rings) was deemed of sufficient structural similarity to uphold a 103

Art Unit: 1624

rejection over unsubstituted counterpart in the prior art. See especially p.425 left column, section 3 regarding the holding of equivalence of various Markush members in the claims originally filed. Thus eg.3 in Jansen, a final product, is still pertinent when instant  $Y=C(O)NH_2$ .

Claims 3, 19 <sup>-21 are</sup> ~~and 20 remain~~ allowed.

**Any inquiry concerning this communication should be directed to Emily Bernhardt at telephone number (703) 308-4714.**

**A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.**

---

*F Bernhardt*  
**EMILY BERNHARDT**

**PRIMARY EXAMINER**

**GROUP 1600**